REMARKS

Status of the Claims:

Claims 1-27 are pending in the application. Claims 13-17 and 23 are canceled without prejudice. Claims 1, 5, 12, 18 and 24-27 have been amended. Claim 1 has been amended herein to clarify the range of the ratio of the dry weight of xylose to that of arabinose in the gel-forming fraction. Claims 28 and 29 are newly presented.

Claim 1 and Claims Dependent Thereon are Not Anticipated by Laidlaw *et al.*

Claims 1-4, 6-11 and 18-23 stand rejected as allegedly anticipated under 35 U.S.C. § 102 by Laidlaw *et al.* (J. Chem. Soc. 1950, pp 528-534) ("Laidlaw I"). The rejection as applied to canceled claim 23 is moot. Applicants respectfully traverse this rejection with respect to the other claims.

Laidlaw I teaches a polysaccharide designated PII which has 80% xylose and 14% arabinose. Thus, PII has a xylose to arabinose ratio of about 5.7 : 1. The instant claim 1 and claims dependent therefrom are directed to a gel fraction from pysillium seed husks comprising xylose and arabinose in a dry weight ratio of at least about 2.5 : 1 to about 4.5 : 1. Since Laidlaw I does not expressly or inherently teach each and every limitation of the instant claims it cannot anticipate them.

Applicants therefore respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

Claim 12 is Not Anticipated by Laidlaw *et al*

Claim 12 stands rejected under 35 U.S.C. § 102 as allegedly anticipated by Laidlaw *et al.* (J. Chem. Soc. 1949, pp 1600-1607) ("Laidlaw II"). Applicants respectfully traverse.

Claim 12 has been amended and is directed a carbohydrate fraction of psyllium seed husks, said fraction being soluble in a dilute alkaline solution and remaining soluble upon acidification of the solution to a pH of about 4.5, said fraction comprising xylose and arabinose in a ratio of at least about 4:1, further comprising at least about 12% (by weight)

rhamnose and at least about 15% (by weight) uronic acid, and further comprising galactose wherein the ratio of the dry weight of the xylose to that of the galactose is about 20:1.

According to the Office Action, Laidlaw II teaches a polysaccharide comprising 46% xylose, 7% arabinose, and 40% 2-D-galacturonosido-L-rhamnose, thus about 20% each of galacturonic acid and rhamnose. Laidlaw II does not teach any galactose. Even if the galacturonic acid content were to be included in the analytical determination of the galactose component, it is not present in the proper ratio and thus Laidlaw II cannot be said to teach a composition with each and every limitation of the claimed gel fraction.

The Claims Are Patentable Over Kennedy *et al.* in view of Laidlaw I.

Claims 24-27 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of Kennedy in view of Laidlaw I. Applicants respectfully traverse the rejection.

The Office Action specifically notes that the claims encompass administration of unfractionated psyllium for constipation. Claims 24-27 have each been amended to clarify that the therapeutic methods are directed to the use of the **isolated** gel fraction, and thus no longer encompass the use of unfractionated pysillium. Since neither Laidlaw I nor Kennedy teach nor suggest the isolated gel fraction of the instant invention, neither of the references, nor the combination can render the claimed invention obvious. For these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

The Claims are Neither Anticipated By Nor Rendered Obvious By Kennedy *et al.*

Claims 18-23 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively under 35 U.S.C. § 103(a) as obvious in view of, Kennedy *et al* (Carb Res. 75-265-274, 1979) ("Kennedy"). With respect to canceled claim 13, the rejection is moot. With respect to claims 18-22, Applicants respectfully traverse. The Office Action concludes that the slight difference in extraction pH is the only difference between the two different methods used to generate the fractions or compositions.

Applicants respectfully note the following:

Kennedy teaches a method of fractionating psyllium husk by alkali treatment with 1.2 M NaOH. They teach removal of alkali-insoluble material, followed by washing with water. The water washes are combined with the alkali-soluble material and neutralized with acid to

form the mucilage. Thus, the Kennedy composition is made by ***extracting, washing and combining***, and ***neutralizing***. (See page 266). Contrary to the assertions in the Office Action, this product *clearly* does not anticipate the composition of claim 18.

The gel fraction of claim 18 is produced by the steps of:

extracting (mixing psyllium seed husks in an aqueous solution comprising (1) a base, wherein if the base comprises hydroxyl ions, the concentration of hydroxyl ions is between about 0.15 and 1.0 M; thereby fractionating the husks into an alkali soluble fraction and an alkali-insoluble fraction);

discarding the alkali-insoluble fraction (removing the alkali-insoluble fraction);

acidifying (acidifying the alkali soluble fraction to a pH of between about 3 and 6, thereby obtaining an acid-insoluble gel fraction, and an acid-soluble carbohydrate fraction); and

separating (separating the gel fraction from the solution containing the acid-soluble carbohydrate fraction).

The differences in the two products are plain: the gel fraction of claim 18 contains no alkali-insoluble, water-soluble material; the gel fraction of claim 18 has the acid soluble material further removed while this material is clearly still present in Kennedy's composition. Kennedy's composition is brought to neutral with acid, but is not acidified, while the gel fraction of claim 18 is a fraction that forms a gel at the acidified conditions of pH 3-6 used in the method for isolating it.

Because Kennedy clearly does not teach the method as used in claim 18, and the composition or fraction obtained is plainly different, Kennedy can not be said to anticipate the gel fraction of claim 18 (or claims dependent thereon). In addition, there is no teaching or suggestion in Kennedy relating to removing the alkali-insoluble material instead of water extracting it. And while there is a teaching of *neutralizing* with acid, contrary to the assertion in the Office Action, there is no teaching or suggestion of *acidifying* to pHs well below neutral, in the range of about 3-6. Because there is no teaching of acidifying, there is clearly no teaching of further removing the acid-soluble fraction from the composition. Because the composition of the gel fraction of claim 18 is ***necessarily*** different from that of Kennedy and

there is no teaching or suggestion of all of the limitations of that gel fraction, Kennedy neither anticipates nor renders claim 18, or claims dependent thereon obvious. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) with respect to the Kennedy reference.

Claim 5 is of Different Scope Than Claim 5 in U.S. Patent No. 6,287,609.

Claim 5 stands rejected for double patenting under 35 U.S.C. §101 as allegedly identical in scope to claim 5 in U.S. Patent No. 6,287,609. Claim 5, as amended is clearly broader in scope than the issued claim, and thus the grounds of the rejection have been obviated.

Applicants thus respectfully request withdrawal of the double patenting rejection.

The Claims in U.S. Patent No. 6,287,609 Do Not Contain All of the Limitations of the Pending Claims

Claims 1-4, 6-12 and 18-23 stand rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly unpatentable over the claims in U.S. Patent No. 6,287,609. Claims 1 and 12 have been amended such that the limitations of these pending claims, and claims dependent thereon, are different from those of the issued claims. Claim 1 and claims dependent thereon are now subject to the limitation of "comprising xylose and arabinose in a dry weight ratio of at least about 2.5 : 1 to about 4.5 : 1". There was previously no upper limit on this ratio, and thus these claim have a different limitation wherein if the patented claims were prior art they would not necessarily anticipate the pending claims.

Similarly claim 12 is now subject to the limitation of "further comprising galactose wherein the ratio of the dry weight of the xylose to that of the galactose is about 20:1." This limitation is not present in the issued claim and those claims would not anticipate pending claim 12.

In view of the foregoing, the grounds of the rejection no longer exist with respect to claims 1 and 12, and thus the Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 12, and claims dependent therefrom or directed to methods utilizing the fractions recited in claims 1 or 12.

Claims 13-17 have been canceled, therefore the obviousness-type double patenting rejection is moot. Claim 18 has been amended to be directed to an isolated psyllium gel fraction produced by the method recited in canceled claim 13. With respect to claim 18 and claims dependent therefrom or directed to methods utilizing the fraction recited in claim 18, Applicants respectfully request that the requirement for a Terminal Disclaimer be held in abeyance pending the determination of allowable subject matter.

Conclusion:

Applicants believe the amendments and arguments presented herein are fully responsive to the Office Action. Applicants respectfully submit that the claims are in condition for allowance. Early and favorable action in that regard are earnestly solicited.

Respectfully submitted,

Date: August 23, 2004

Scott E. Scioli
Registration No. 47,930

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439